DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 22, 2015

Acuitas Medical Ltd.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
WASHINGTON DC 20004

Re: K150069
Trade/Device Name: Fine Structure Analysis (***fine***SA) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, LNH
Dated: April 22, 2015
Received: April 22, 2015

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K150069

Device Name

Fine Structure Analysis (***fine****SA*) Software

Indications for Use *(Describe)*

fineSA software is intended for use as a non-invasive device that processes designated MR images using the 2-D pulse sequence incorporated on Siemens Medical 3T MAGNETOM systems running syngo MR software versions B17 and D13. This includes the Aera, Skyra, Avanto and Verio models.

fineSA software generates reports that provide information about the structural features in bone. The MR data, in the form of spectra or spectral images, reflect the spacing of structural features at a scale of approximately 500 microns or larger.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY (K150069)
AS REQUIRED BY 21 CFR 807.92(c)

1. Submitter

Acuitas Medical Ltd.
12 Technium One, Kings Road
Swansea Waterfront
SA1 8PH Wales UK

Phone: (970) 472-0613
Fax: (970) 416-8896

Contact Person:
John Heinrich, Ph.D.
Chief Executive Officer
Phone: (970) 472-0613
Fax: (970) 416-8896
Email: jheinrich@acuitasmedical.com

2. Date Prepared

May 20, 2015

3. Device

- Trade Name: Fine Structure Analysis (***fine***SA)
- Common Name: System, Image Processing, Radiological
- Classification Name: Picture Archiving and Communication System (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: LLZ, LNH

4. Predicate Device

The predicate device for the Fine Structure Analysis (***fine***SA) software is the syngo.MR General, which was cleared under 510(k) K130749.

5. Device Description

fineSA is a tool for the characterization of trabecular bone microarchitecture using magnetic resonance data. ***fine***SA analyzes data acquired from a region of interest with a 2-D pulse sequence. The result is a spectrum that shows not chemical information, but the average spacing of the structural elements within the region of interest. ***fine***SA provides the ability to identify repetitive structural features as small as 500 μm.

Compatible MRI scanners, acquire one-dimensional data along the length of a defined region of interest in the anatomical region using a standard pulse sequence available on the OEM scanner. The additional acquisition time required to collect the ***fine***SA compatible data is less than 2 minutes. The resulting DICOM data object is transferred to a network personal computer loaded with ***fine***SA software for processing and report generation.

The DICOM input data is received from the MRI scanner via standard DICOM protocols. The processing performed is driven by the received data content, and at the completion of data processing and analysis, a PDF formatted report is generated and transferred to a designated DICOM destination as a DICOM encapsulated PDF document for viewing and interpretation.

fineSA is a software only image processing system that can be installed on any network computer that meets the specified minimum hardware and operating system requirements. The system can be deployed on the radiology internal network or at a remote location with secure access to radiology internal network.

6. Indications for Use

fineSA software is intended for use as a non-invasive device that processes designated MR images using the 2-D pulse sequence incorporated on Siemens Medical 3T MAGNETOM systems running syngo MR software versions B17 and D13. This includes the Aera, Skyra, Avanto and Verio models.

fineSA software generates reports that provide information about the structural features in bone. The MR data, in the form of spectra or spectral images, reflect the spacing of structural features at a scale of approximately 500 microns or larger.

7. Predicate Device Comparison

The ***fine***SA software is substantially equivalent to the syngo.MR General post-processing application (K130749).

A summary comparison of characteristics is provided in Table 1.

Table 1 - fineSA & Predicates Comparative Analysis

Characteristic	Fine Structure Analysis (*fine*SA)	PREDICATE syngo.MR General
510(k) Clearance	K150069	K130749
Imaging Modality	MRI	MRI
Product Code	LLZ	LLZ
Intended Use	***fine***SA software is intended for use as a non-invasive device that processes designated MR images using the 2-D pulse sequence incorporated on Siemens Medical 3T MAGNETOM systems running syngo MR software versions B17 and D13. This includes the Aera, Skyra, Avanto and Verio models. ***fine***SA software generates reports that provide information about the structural features in bone. The MR data, in the form of spectra or spectral images, reflect the spacing of structural features at a scale of approximately 500 microns or larger.	Post processing software / applications to be used for viewing and evaluating the designated images provided by a magnetic resonance device. syngo.MR General is a syngo based post-processing software for viewing, manipulating, and evaluating MR images.
Software Device	Yes	Yes
Patient Contact	No	No
Graphical User Interface (GUI)	No	Yes
Data Interchange	DICOM	DICOM
Data Acquisition	Data acquired for fineSA processing uses spin echo and gradient echo sequences.	Data acquired uses spin echo and gradient echo sequences.
Data Analysis	Data analyzed using standard data analysis techniques including Fourier and inverse Fourier transformations and windowing.	Data analyzed using standard data analysis techniques including Fourier and inverse Fourier transformations and windowing.
Data Presentation	Data presented in conjunction with MR images.	Data presented as or in conjunction with MR images.
Data Types	Spacings of anatomical elements in bone.	Various, including anatomical, relaxation time, diffusion rate, spectroscopic, and chemical shift.

8. Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "moderate" level of concern, since a malfunction or latent flaw in the software could delay delivery of appropriate medical care that would likely lead to minor injury.

The ***fine***SA processing software was fully tested, verified and validated by Acuitas as part of its internal design control requirements to ensure it meets defined specifications using phantom and clinical data. Formal test plans were executed to confirm that ***fine***SA meets its formal requirements. This submission includes the verification and validation plan, test results, and verification and validation report confirming the ***fine***SA meets its intended use and performance requirements.

9. Risk Management

Product risk management activities were performed in accordance with ISO 14971:2007 throughout the product development process. Risk management verification and validation consisted of both a desk audit and software testing to ensure the implementation of all risk mitigations for the device.

10. Substantial Equivalence Conclusion

As noted previously, the ***fine***SA and its predicate devices have similar intended use for viewing and evaluating the designated images provided by a magnetic resonance device. While there are some differences between fineSA and its predicates, these differences are minor and do not raise different questions of safety and effectiveness. Performance data and software verification and validation demonstrate that the fineSA software should perform as intended in the specified use conditions.

Therefore, Acuitas Medical believes that the fineSA software is substantially equivalent to the predicate devices identified in this submission.